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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/133,766	08/12/1998	BIRGIT ANNA HELM	HELM-ET-ALPC	6988

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE N.W.
WASHINGTON, DC 20037-3213

EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/133,766

Applicant(s)

Helm et al.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-53 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

1. The request filed on 6/7/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/133766 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 44-53 are under consideration. Claims 34-43 have been canceled.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 45 and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the method of claim 45 wherein the cell-line is "sensitized prior to said exposing". This step is not disclosed in the particular passages of the specification to which applicant refers. Furthermore, claim 44 specifically recites that the substance is added to the mast cell-line in the absence of a "sensitizing agent". The only disclosure of "sensitized" mast/basophil cells in the specification is cells sensitized by the addition of IgE (a sensitizing agent). Regarding Example 2, said example refers to specific assays using bee venom lipase. Furthermore, said example refers to two different assays (eg. one without sensitizing agent and one assay using sensitizing agent). It does not disclose use of sensitized cells in an assay wherein sensitizing agent is not added.

There is no support in the specification as originally filed for the method of claim 47. Said limitation is not disclosed in any of the passages disclosed in the specification to which applicant refers. To the extent that said limitation is based on figure 4, said figure refers to release of radiolabeled 5HT in response to bee venom phospholipase. This is not a disclosure of the scope of claim 47.

There is no support in the specification as originally filed for the scope of the claimed

invention (eg. the claimed invention constitutes new matter).

5. Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the method of claim 45. Claim 44 specifically recites that the substance is added to the mast cell-line in the absence of a "sensitizing agent". The only sensitized mast cells and or basophil cells disclosed in the specification are those sensitized by the addition of a "sensitizing agent" (eg. IgE which binds the antigen in the assay). Thus, claim 44 recites that the assay is performed in the absence of a sensitizing agent, whilst the method of claim 45 requires a sensitizing agent (eg. the cell would not be sensitized until IgE was added and present on the cell surface). Thus, the specification is not enabling for the method of claim 45.

6. Claims 44-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed method. Benyon et al. teach that a variety of self proteins and other molecules which are not allergens (eg. compound 48/80, poly-L-lysine, substance P, VIP, somatostatin (see page 898, second column)) cause the release of the mediator histamine from mast cells. Said substances are not allergens. In fact, Benyon et al. refer to the release of histamine by mast cells in response to the aforementioned substances as cause by "non-immunological stimuli". While Benyon et al. also disclose that specific different specific mediators are released by IgE versus IgE independent mast cell activation, the instant claims do not recite release of any particular mediator. Thus, the claimed invention could not be used to determine the allergenicity of a substance because nonallergens also cause the release of mediators from mast cells. In fact, Benyon et al. disclose that nonallergens can cause the release of histamine from mast cells in similar amounts to that seen when allergens are used in the assay. The claimed invention encompasses a method wherein histamine is the only mediator assayed (eg. see claim 50). Furthermore, if the agent causes release of mediators from mast cells in the absence of IgE, using the assays disclosed in the specification it would not be possible to determine if the agent was an allergen per se (eg. capable of inducing IgE antibodies) because the agent causes release of

mediators from mast cells in the absence of IgE. Therefore, the specification is not enabling for the claimed invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 44-53 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.


Claim 45 lacks antecedent basis in claim 44. Claim 44 specifically recites that the substance is added to the mast/basophil cell in the absence of a "sensitizing agent". The only sensitized mast cells and or basophil cells disclosed in the specification are those sensitized by the addition of a "sensitizing agent" (eg. IgE which binds the antigen in the assay). Thus, claim 44 recites that the assay is performed in the absence of a sensitizing agent, whilst the method of claim 45 requires a sensitizing agent (eg. the cell would not be sensitized until IgE was added). Claims 44 is indefinite in the recitation of "sensitizing agent" because it is unclear what this term means or encompasses. While the specification discloses a specific example of a sensitizing agent (IgE which binds a particular allergen), it is unclear as to what other agents would or would not constitute a sensitizing agent. This term is not defined in the specification and it has no art recognized meaning. Claims 45 and 46 are indefinite in the recitation of "sensitized" because it is unclear as to what this term means in the context recited in the claims. While the specification discloses a specific example of a sensitizing agent (IgE which binds a particular agent), which presumably leads to "sensitized" mast cells when cells are treated with said agent, it is unclear as to what other treatments would or would not render a mast cell "sensitized". Claim 47 is indefinite in the recitation of "high-secretor variant" because it is unclear what this term means or encompasses in a quantitative sense. It is unclear as to what differentiates a high secretor from a low secretor versus an average secretor.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.


RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600 l6cs

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644